AUG 10 2012

510(k) Summary: Multix Fusion X-ray System

Company: Siemens Medical Systems, Inc.
1 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: July 26, 2012
This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. **General Information:**

Importer / Distributor:
Siemens Medical Solutions, Inc.
51 Valley Stream Parkway, E-50
Malvern, PA 19355
Establishment Registration Number: 2240869

Location of Manufacturing Site:
Siemens AG
Medical Solutions
X-Ray Products
Henkestrasse 127
DE-91052 Erlangen
Establishment Registration Number: 3002808157

Manufacturer:
Siemens Shanghai Medical Equipment Ltd.
278 Zhou Zhu Road, Shanghai
201318, China
Headquarters:
Siemens AG
Wittelsbacherplatz 2
D-80333 Munich 2, Germany
Establishment Registration Number: 3003202425

2. **Contact Person:**
Ms. Patricia D Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway D-02
Malvern, PA 19355
Phone: (610) 448 -3536 Fax: (610) 448-1787

Email: patricia.d.jones@siemens.com

3. **Device Name and Classification:**

Trade Name:	Multix Fusion
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology

Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	90 KPR

4. **Legally Marketed Predicate Device**

Trade Name:	Ysio
510(k) #:	K0817227
Clearance Date:	August 22, 2008
Classification Name:	Solid State X-ray Imager (SSXI)
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1680
Device Class:	Class II
Product Code:	90 MQB

5. **Device Description:**

The Multix Fusion is a modification of Siemens' Ysio X-ray system cleared under Premarket Notification K081722 on 08/22/2008. The Multix Fusion offers the following system configurations:

- An analog radiography system or;
- A digital radiography system with a mobile (wired) and/or a portable (wireless) flat panel detector or;
- An optional Multix DR-Upgrade for the analog version of the Multix Fusion and other tables within the Multix and Vertix analog family.

This modification does not affect the general intended use of the device nor does it alter its fundamental scientific technology.

The Multix Fusion system consists of a radiologic table, x-ray generator, x-ray tube, flat panel detector (wired or wireless) and Bucky-wall stand. It will be marketed as an analog system, a digital radiographic system with a mobile (wired) and/or portable (wireless) flat panel detector or an optional Multix DR- Upgrade for the analog version of the Multix Fusion and other tables within the Multix and Vertix analog family.

The key components are a patient table, a ceiling mounted support and a Bucky wall stand which are available in different configurations. A semi-motorized movement in the ceiling-mounted X-ray tube is available. The optional Multix DR-Upgrade for the analog version of the Multix Fusion consists of a mobile (wired) and/or portable (wireless) flat panel detector and an imaging system. Components used to upgrade (Multix DR-Upgrade) the analog version of the Multix Fusion and other tables within the Multix and Vertix analog family are the same or similar components cleared in the Ysio 510(k) K0817227 on August 22, 2008.

The Multix Fusion may be combined into different configurations to provide specialized customer requirements.

Similar to the cleared Ysio stationary x-ray system, the Multix Fusion and the Mutix DR-Upgrade have the same or similar comparable components. The subject device the Multix Fusion does not affect the indication for use nor the intended use of the device nor does it alter its fundamental scientific technology.

6. **Indication for Use:**
The Multix Fusion system is a radiographic system used in hospitals, clinics, and medical practices. Multix Fusion enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. It can also be used for intravenous, small interventions (like biopsy, punctures, etc.) and emergency (trauma, critical ill) applications. Exposures may be taken with the patient sitting, standing, or in the prone position. The Multix Fusion system is not meant for mammography.

The Multix Fusion uses a mobile (wired) or portable (wireless) digital detector for generating diagnostic images by converting x-rays into electronic signals. The Multix Fusion is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.

7. **Substantial Equivalence:**
The Multix Fusion is substantially equivalent to the commercially available Siemens Ysio radiographic x-ray system. The Ysio was described in premarket notification K081722 which received FDA Clearance on August 22, 2008. Ysio is indicated for tomographic procedures, The Multix Fusion is not indicated for tomographic procedures. The technical differences between the Multix Fusion and the Ysio are listed below:

Table 1: Subject and Predicate Device Comparable Properties

Comparable Properties	Subject Device Multix Fusion	Predicate Device Ysio (K081722)	Comparison Results
X-ray tube	80 kW Two-focus	80 kW Two-focus	Same
Flat panel detector portable	43cm x 36 cm Type: 4336X	43cm x 36 cm Type: 3543pR	Same imaging technology
Digital Imaging system	Fluorospot Compact High Res Digital Imaging	Fluorospot Compact High Res Digital Imaging	Similar Functionality
Collimator	ACSS collimator (Automatic Cassette Size Sensing)	ACSS collimator (Automatic Cassette Size Sensing)	Similar Functionality
X-ray Generator	80 kW 65 kW 55 kW	80 kW 65 kW	Similar
Conventional film/screen systems or CR cassettes	Film/Screen or CR Cassettes	Film/Screen or CR Cassettes	Same

8. **Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:**
The Multix Fusion does not have significant changes in materials, energy source, or technological characteristics when compared to the predicate device. The intended use and fundamental scientific technology are similar to the predicate device. The Multix Fusion is designed based on the Ysio radiography x-ray system. It uses the same or similar components cleared in the Ysio (e.g. tube, generator, ceiling-mounted tube support, table, Bucky wall stand and imaging system). The Multix Fusion is similar to the predicated system with respect to technical characteristics,

performance and intended use. The subject device the Multix Fusion does not affect the indication for use nor the intended use of the device nor does it alter its fundamental scientific technology.

9. **Non-clinical Testing:**
Non-clinical testing was conducted for the Multix Fusion during product development. This includes verification and validation testing as well as phantom testing. The risk analysis was completed and risk controls implemented to mitigate identified hazards. The testing results supports that all the software specificatins have met the acceptance criteria.

Testing for verification and validation of the device was found acceptable to support the claims of substantial eqivalence.

10. **General Safety and Effectiveness Concerns:**
Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner. Several safety features including visual and audible warnings are incorporated into the system design. In addition the Multix Fusion is continually monitored, and if an error occurs, the system functions will be blocked and an error message will be displayed.

Furthermore the operators are health care professionals familiar with and responsible for the evaluating and post processing of X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

11. **Conclusion as to Substantial Equivalence:**
The Multix Fusion is intended for the same use as Ysio (with the exception of tomography). It uses the same or similar components cleared for the Ysio (e.g. tube, generator, ceiling-mounted tube support, table, Bucky wall stand and imaging system). It is Siemens opinion, that the Multix Fusion is substantially equivalent to the cleared predicate device the Ysio radiographic x-ray system.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

AUG 10 2012

Ms. Patricia D. Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway, E-50
MALVERN PA 19355

Re: K121513
Trade/Device Name: Multix Fusion
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: July 26, 2012
Received: July 27, 2012

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K121513

Indications for Use Statement

510(k) Number (if known): K121513

Device Name: Multix Fusion

Indications for Use:

The Multix Fusion system is a radiographic system used in hospitals, clinics, and medical practices. Multix Fusion enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. It can also be used for intravenous, small interventions (like biopsy, punctures, etc.) and emergency (trauma, critical ill) applications. Exposures may be taken with the patient sitting, standing, or in the prone position. The Multix Fusion system is not meant for mammography.

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K121513